

10/53384

JC14 Re PCT/PTO 28 APR 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ruediger Ridder, *et al.*

Application Serial No.: Not Yet Assigned

Filed: Herewith

For: METHOD FOR IMPROVED  
DIAGNOSIS OF DYSPLASIAS

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Attorney's Docket No.:05033.0010.PCUS00

**Information Disclosure Statement**

Mail Stop PCT  
Attention: DO/EO/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

The Examiner is specifically requested not to rely solely on the material submitted herewith.

It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
  - a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
  - b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - c. Before the mailing date of a first Office Action on the merits;
  - d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

- 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
  - c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

- 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i), and
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- 4. Relevance of the non-English language document(s) is discussed in the present specification.
- 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- 8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

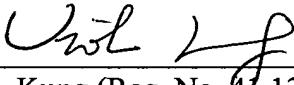
10/533384  
JC14 Rec'd PCT/PTO 28 APR 2005  
Attorney Docket No. 05033.0010.PCUS00

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05033.0010.PCUS00.

Respectfully submitted,

Date: April 28, 2005

  
\_\_\_\_\_  
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<b>INFORMATION DISCLOSURE CITATION</b>  <b>SUPPLEMENTAL PTO-1449</b>	ATTY. DOCKET NO. 05033.0010PCUS00	SERIAL NO. <b>10/533384</b> Not yet Assigned
	APPLICANT : RIDDER, Ruediger, et al.	
	FILING DATE	GROUP Not yet Assigned

**U.S. PATENT DOCUMENTS**

EX'R INITIAL	PATENT NO.	DATE MM-YYYY	NAME	CLASS	SUBCLASS	FILING DATE
	143646 A1	07/31/2003	Williams Gareth H et al.			
	6303323 B1	10/16/2001	Williams Gareth H et al.			
	5723313 A	03/03/1998	St. Jude Chil. Res. Hosp.			
	6172194 B1	01/09/2001	St. Jude Chil. Res. Hosp.			
	6407062 B1	06/18/2002	St. Jude Chil. Res. Hosp.			
	6482929 B1	11/19/2002	St. Jude Chil. Res. Hosp.			
	5876965 A	03/02/1999	St. Jude Chil. Res. Hosp.			

**FOREIGN PATENT DOCUMENTS**

EX'R INITIAL	PATENT NO.	DATE MM-YYYY	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	EP 1 387 173 A	02/04/2004	mtm laboratories AG				
	WO 04 013631 A2	02/12/2004	mtm laboratories AG				
	WO 02 08764 A	01/31/2002	Medical Res. Council				
	WO 01 40300 A	06/07/2001	DKFZ				
	WO 97 12060	04/03/1997	St. Jude Chil. Res. Hosp.				
	EP 0853681 A1	07/22/1998	St. Jude Chil. Res. Hosp.				
	WO 9921014 A1	04/29/1999	Williams Gareth H et al.				
	EP 1025444 A1	08/09/2000	Williams Gareth H et al.				

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EX'R INITIAL	DOCUMENT
	BEPLER G ET AL: "Mcm2: A novel diagnostic marker for early detection of premalignant lesions of the lung", PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH ANNUAL, vol. 42, 2001-03, p. 356
	KLAES R ET AL: "Overexpression of p16(INK4a) as a specific marker for dysplastic and neoplastic epithelial cells of the cervix uteri", Int. Journal of Cancer, vol. 92, no.2, 2001-04-15, p. 276-284
	RIDDER R ET AL: "Novel biomarkers for HPV associated lesions", Gynäkologe 01, vol.36, no. 4, 2003-04-01, p. 323-330

	RIETHDORF LUTZ ET AL: "Human papillomaviruses, expression of p16INK4a, and early endocervical glandular neoplasia", Human Pathology, vol. 33, no. 9, 2002-09, p. 899-904
	SÁNCHEZ-AGUILERA ABEL ET AL: "p14(ARF) nuclear overexpression in aggressive B-cell lymphomas is a sensor of malfunction of the common tumor suppressor pathways", Blood, vol. 99, no. 4, 2002-02-15, p. 1411-1418
	SANO T ET AL: "Expression status of p16 protein is associated with human papillomavirus oncogenic potential in cervical and genital lesions", American Journal of Pathology, vol. 153, no.6, 1998-12, p. 1741-1748
	SIMONART THIERRY ET AL: "Antiproliferative and apoptotic effects of iron chelators on human cervical carcinoma cells", Gynecologic Oncology, vol. 85, no.1, 2002-04, p. 95-102
	VON KNEBEL DOEBERITZ MAGNUS: "New markers to identify HPV-transformed dysplastic cervical epithelia", Acta Cytologica, vol. 46, no.1 Supplement, 2002-01, page 156

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

\*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).